

137. A method for producing the protein of claim 133, comprising:
- (a) culturing a host cell under conditions suitable to produce the protein; and
 - (b) recovering the protein from the cell culture.
138. The protein of claim 133, which comprises a heterologous polypeptide.
139. A composition comprising the protein of claim 133 and a pharmaceutically acceptable carrier.
140. An isolated protein produced by a method comprising:
- (a) expressing the protein of claim 133 in a cell; and
 - (b) recovering the protein.--

Remarks

After cancellation of claims 62-67 and entry of the foregoing amendments, claims 24-27, 68-70, 77-80 and 90-140 will be pending in the application, with claims 70, 90, 98, 106, 114, 121, and 133 being the independent claims.

I. The Amendments to the Specification

The amendments set out above are required to bring the specification into conformity with the formal drawings submitted herewith. Support for the above amendments is found throughout the specification and the originally filed figures. None of these amendments introduce new matter.

II. The Restriction Requirement

In Paper No. 11, the Examiner restricted the claims into the following groups:

- I.** Claims 62-67 and 90-127, drawn to a polypeptides of SEQ ID NO:4, isolated proteins encoded by polynucleotides which hybridize to SEQ ID NO:3 and a method of producing the polypeptide of SEQ ID NO:4, classified in class 514, subclass 2 and class 435, subclass 69.1.
- II.** Claims 24 and 68, drawn to antibodies which bind to the polypeptides of SE ID NO:4 and antibodies which bind to the polypeptides encoded by polynucleotides which hybridize to SEQ ID NO:3, classified in class 424, subclass 130.1.
- III.** Claims 25 and 69, drawn to a method of detecting the polypeptides of SEQ ID NO:4 and polypeptides encoded by polynucleotides which hybridize to SEQ ID NO:3, classified in class 435, subclass 4.
- IV.** Claims 26 and 27, drawn to a method of treatment comprising the administration of the polypeptide of SEQ ID NO:4, classified in class 530, subclass 387.1.
- V.** Claim 70, drawn to a polypeptide of SEQ ID NO:8, classified in class 514, subclass 2.
- VI.** Claim 77, drawn to an antibody which binds the polypeptide of SEQ ID NO:8, classified in class 424, subclass 130.1.
- VII.** Claim 79 and 80 drawn to a method of treatment comprising the administration of the polypeptide of SEQ ID NO:8, classified in class 530, subclass 350.
- VIII.** Claim 78 drawn to a method for detecting the polypeptide of SEQ ID NO:8, classified in class 435, subclass 4.

Applicants respectfully traverse the restriction requirement as it applies to each of Groups

I-VIII.

In brief, it is the Examiner's position that Group I-VIII "are distinct and . . . have acquired a separate status in the art" (Paper No. 11, page 4.)

Applicants point out that, even where two patentably distinct inventions appear in a single application, restriction remains improper unless the Examiner can show that the search and examination of both groups would entail a "serious burden". (*See* M.P.E.P. § 803.) In the present situation, the Examiner has failed to make such a showing.

With respect to Galectin 9 (Groups I-IV) and Galectin 10SV (Groups V-VIII) in general, Applicants note that these proteins have similar functional activities. Thus, searches of the subject matter of Groups I-VIII would clearly be overlapping.

Applicants also note that the subject matter of Groups II-IV (antibodies, detection methods, and methods for treating disorders) are each linked to the Galectin 9 proteins of Group I. Further, the subject matter of Groups VI-VIII (antibodies, detection methods, and methods for treating disorders) are each linked to the Galectin 10 proteins of Group V. Thus, Applicants again note that searches of the subject matter of Groups I-VIII would clearly be overlapping.

In view of the above comments, Applicants assert that examination of the subject matter of Groups I-VIII would not entail a "serious burden" and the restriction requirement should be withdrawn.

Applicants further note that, as a result of the decisions in *In re Ochiai*, 37 U.S.P.Q.2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 37 U.S.P.Q.2d 1663 (Fed. Cir. 1996), a notice was published in the Official Gazette which sets forth guidelines for the treatment of biotechnological product and process claims. *See* 1184 O.G. 86 (March 26, 1996). This notice states in relevant part:

[W]here product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or the process. . . . However, in the case of an elected product

claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim.

1184 O.G. 86 (March 26, 1996).

As Applicants pointed out in the Reply to Restriction Requirement and Third Preliminary Amendment filed in the captioned application on August 4, 2000, claims 26-27 are directed to processes for using isolated proteins of claim 90. Applicants thus respectfully request that the Examiner rejoin and examine for patentability these process claims if claim 90 is found to be in condition for allowance.

Further, claims 79-80 are directed to processes for using isolated proteins of claim 70. Applicants thus respectfully request that the Examiner rejoin and examine for patentability these process claims if claim 70 is examined and found to be in condition for allowance.

Applicants note that claims 90-140 represent the subject matter of Group I, which is provisionally elected herein.

Conclusion

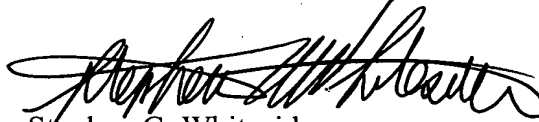
It is respectfully believed that this application is now in condition for substantive examination. Early notice to this effect is respectfully requested.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor

(including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Stephen G. Whiteside", written over a horizontal line.

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